Que Duración para la Doble Agregación Plaquetaria?

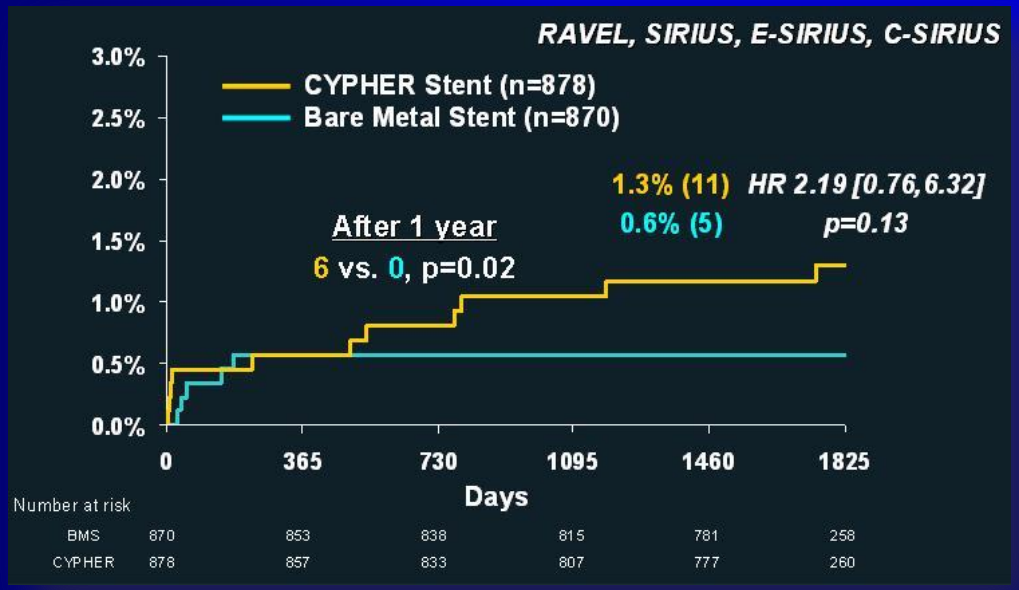
Lima- Perú

Stents Farmacológicos

Trombosis – 5 años

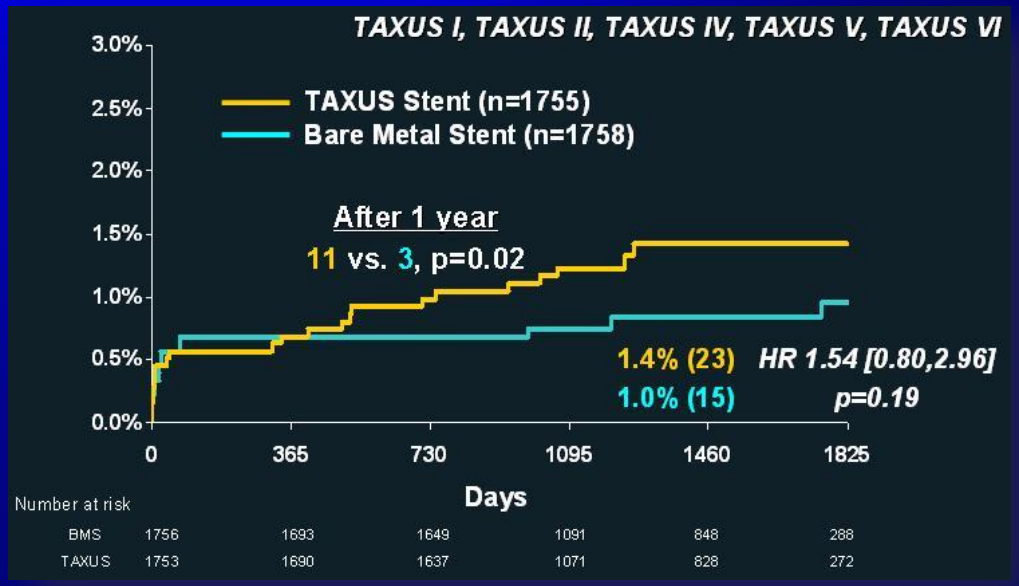
n = 1.748

Ravel, Sirius, C – Sirius, E – Sirius



n = 3.503

Taxus I, II, IV, V, VI



Stone G. N Engl J Med 2007;356:998-1008

PCI FOCUSED UPDATE

2007 Focused Update of the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention

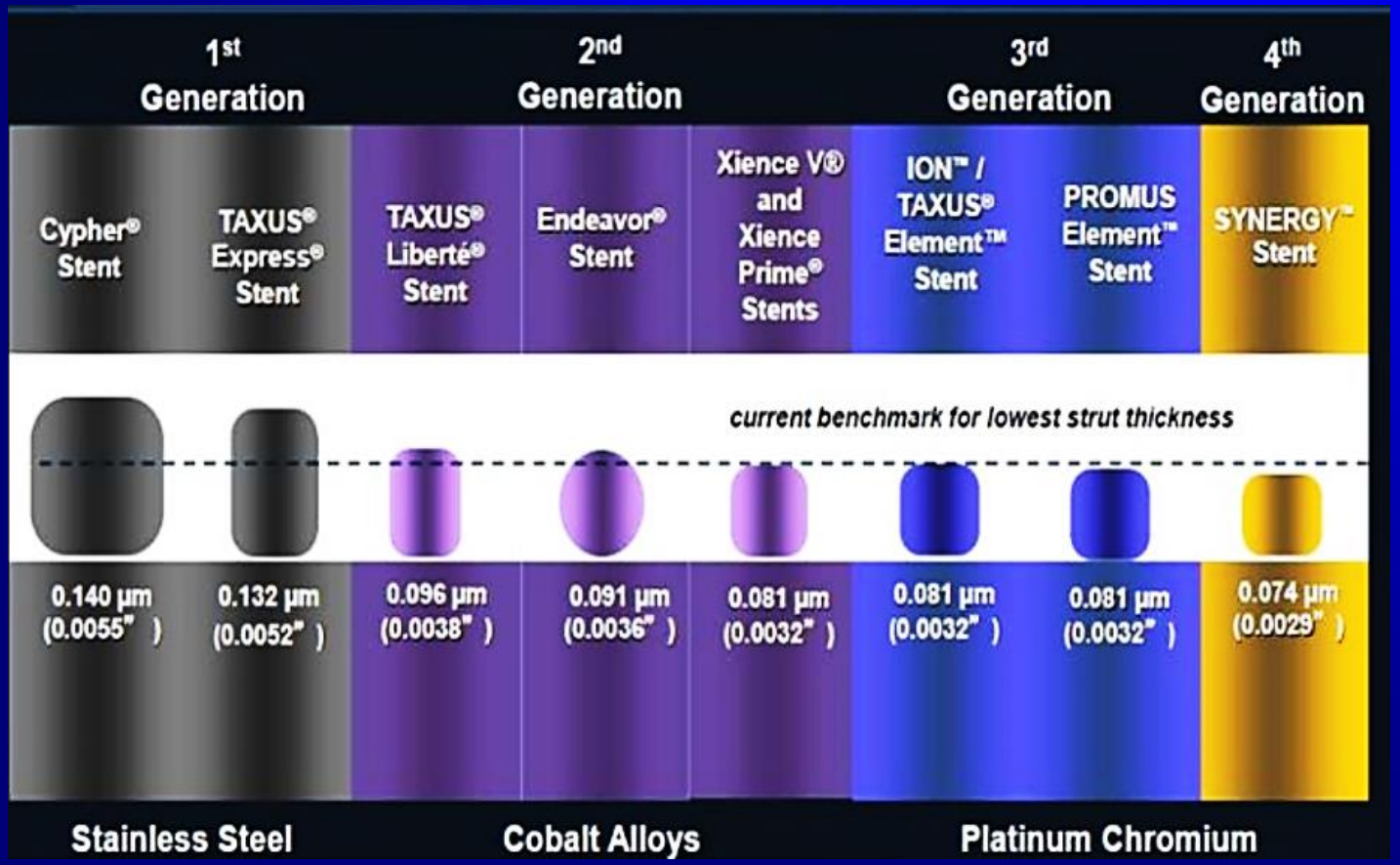
A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

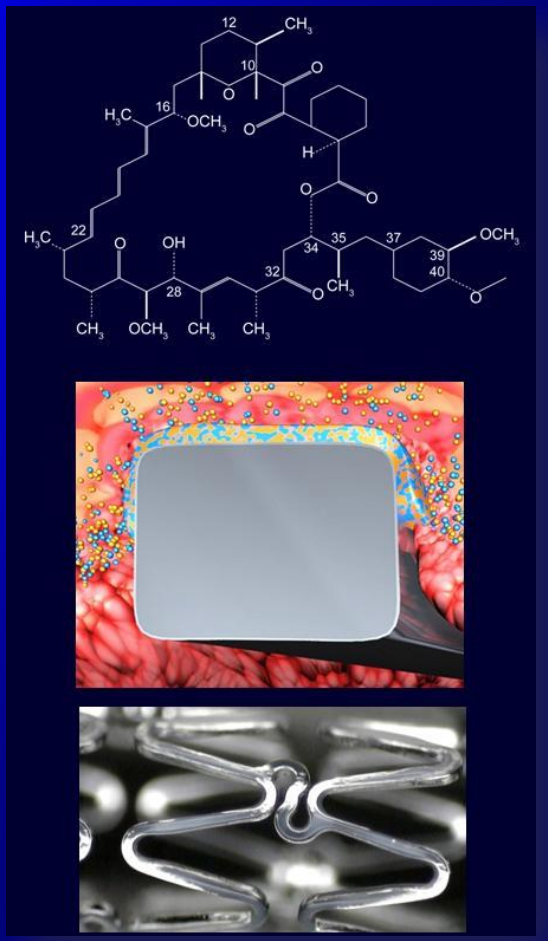
Table 14. Updates to Section 6.2.1: Oral Antiplatelet Therapy

2005 PCI Guideline Update Recommendation	2007 PCI Focused Update Recommendation
	Class I
In patients who have undergone PCI, clopidogrel 75 mg daily should be given for at least 1 month after bare-metal stent implantation (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks), 3 months after sirolimus stent implantation, and 6 months after paclitaxel stent implantation, and **ideally up to 12 months** in patients who are not at high risk of bleeding. *(Level of Evidence: B)*	For all post-PCI stented patients receiving a DES, clopidogrel 75 mg daily should be given for **at least 12 months** if patients are not at high risk of bleeding. For post-PCI patients receiving a BMS, clopidogrel should be given for a minimum of 1 month and **ideally up to 12 months** (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks). *(Level of Evidence: B)*

King III S.B. J Am Coll Cardiol 2008;51:172-209

Stents Farmacológicos
Evolución Tecnológica



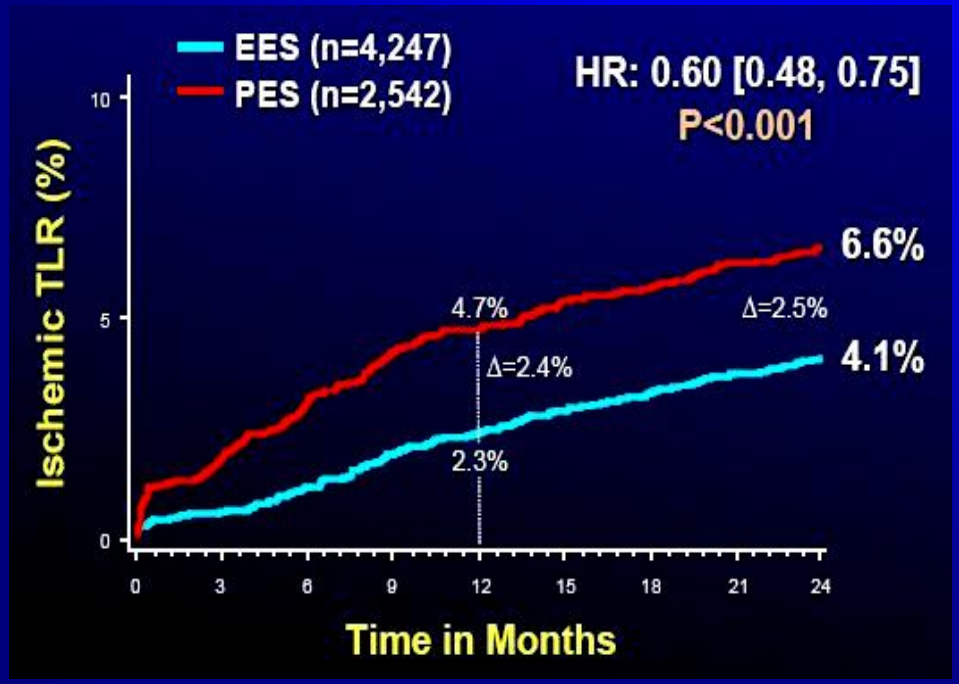


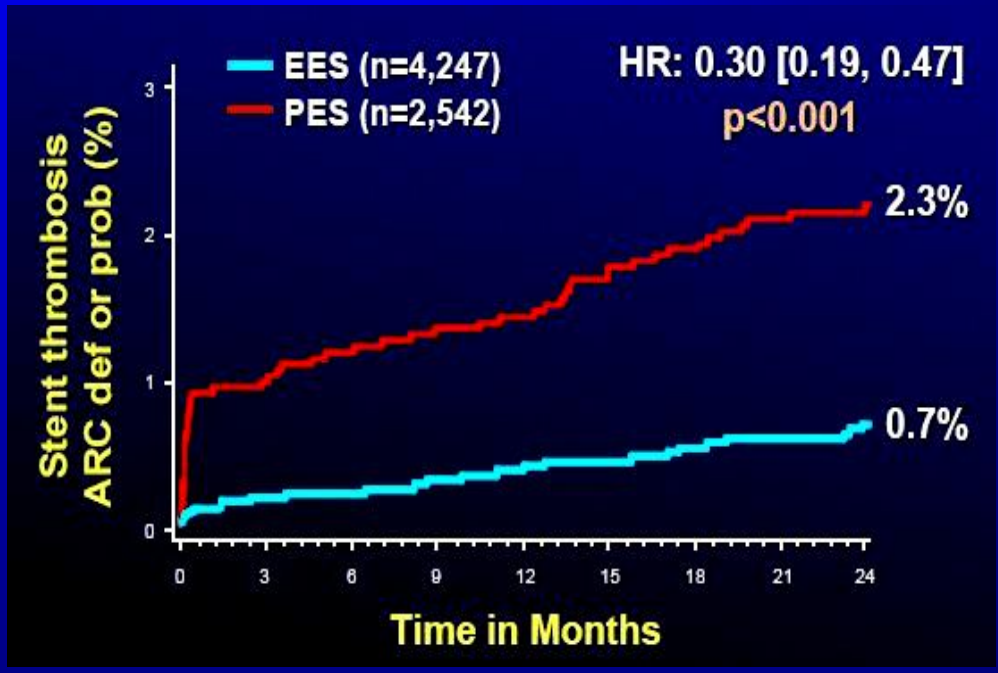
Polímero de Ácido Polilático Bioabsorbible

SPIRIT II/III/IV e COMPARE Trials

Análise Conjunta de Dados

n = 6.789

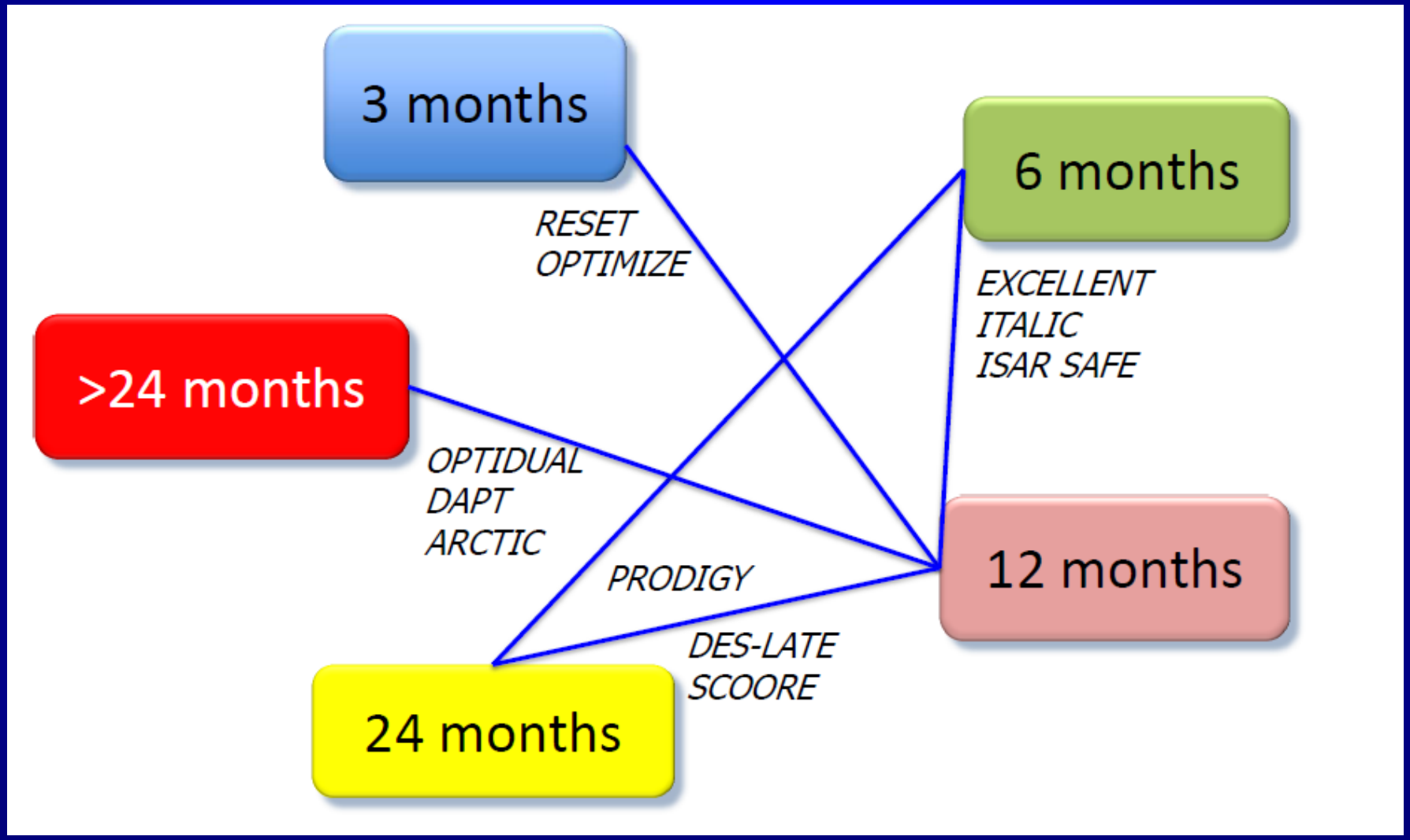




Kedhi E. Eurointervention 2012;8:599-606

Duración de la DAPT

Estudios Randomizados



Doble Agregación Plaquetária

¿Qué camino seguir?

Meta-análisis DES

Estudios Randomizados 3 o 6 m vs 12 m

n = 8.180

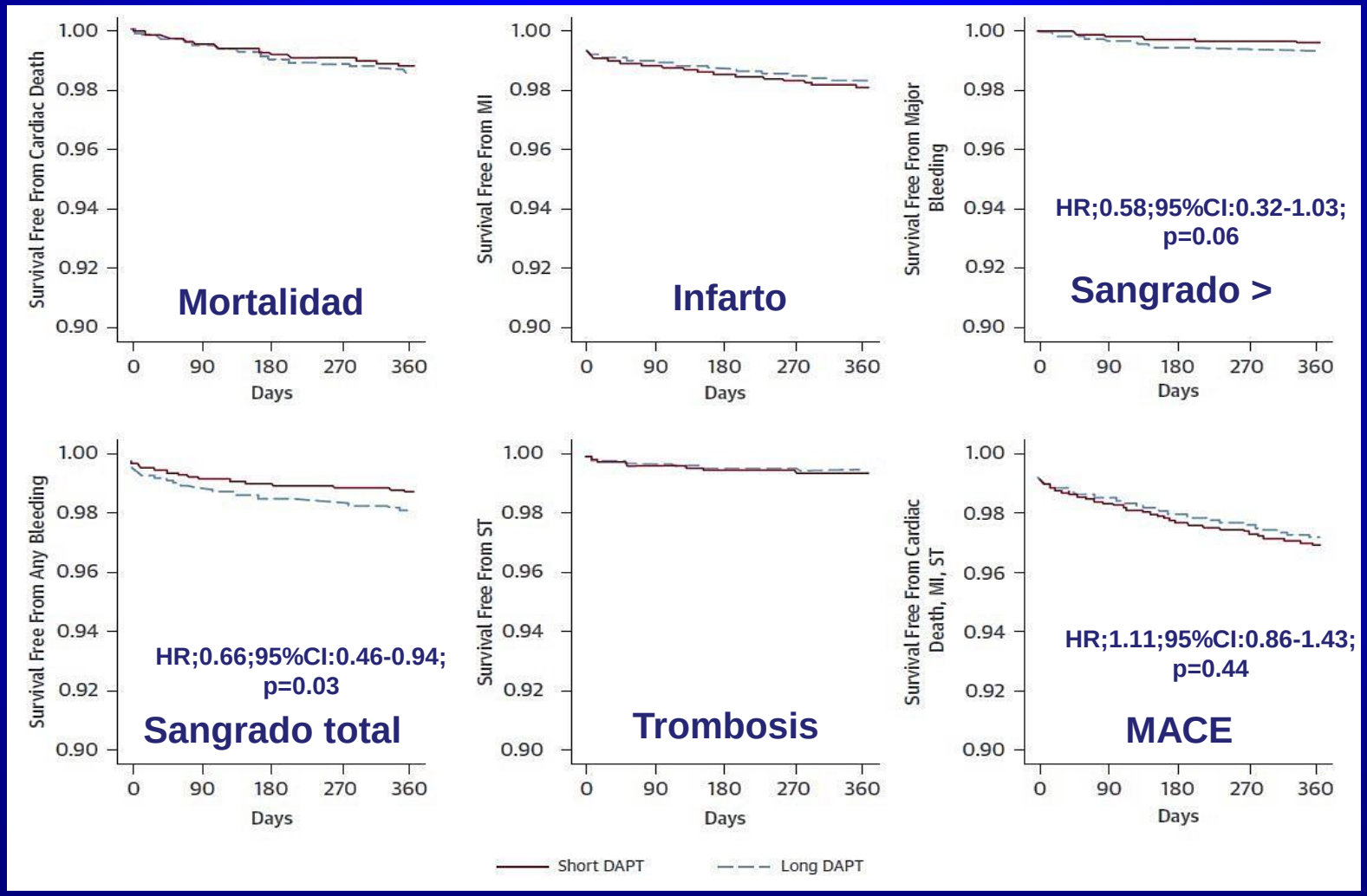
TABLE 1 Main Characteristics of Randomized Trials Included in Meta-Analysis

Study (Ref. #)	n	Primary Endpoint	Design	Follow-Up	DAPT Duration (Months)	Primary Endpoint Results
EXCELLENT (13)	6 months (n = 722) 12 months (n = 721)	Cardiac death/MI/ischemia-driven TVR	Noninferiority	1 yr	6 vs. 12	Noninferiority demonstrated
OPTIMIZE (12)	3 months (n = 1,563) 12 months (n = 1,556)	Death/MI/CVA/major bleeding	Noninferiority	1 yr	3 vs. 12	Noninferiority demonstrated
PRODIGY (16)	6 months (n = 751) 12 months (n = 750)	Death/MI/CVA	Superiority	2 yrs	6 vs. 24	Superiority of 24-month DAPT not demonstrated
RESET (14)	3 months (n = 1,059) 12 months (n = 1,058)	Cardiac death/MI/ST/TVR/major bleeding	Noninferiority	1 yr	3 vs. 12	Noninferiority demonstrated

Palmerini T. J Am Coll Cardiol 2015;65:1092-1102

Meta-análisis DES

Estudios Randomizados 3 o 6 m vs 12 m



Palmerini T. J Am Coll Cardiol 2015;65:1092-1102

DAPT STUDY

12 vs 30 meses

11 Países 452 Centros n = 9.961

12 meses pós ICP SF c/ DAPT non presentaran MACCE, Nueva Revascularización, Sangrado Moderado o Severo

n = 4.941	n = 5.020
Placebo + AAS 18 m	DAPT 18 m

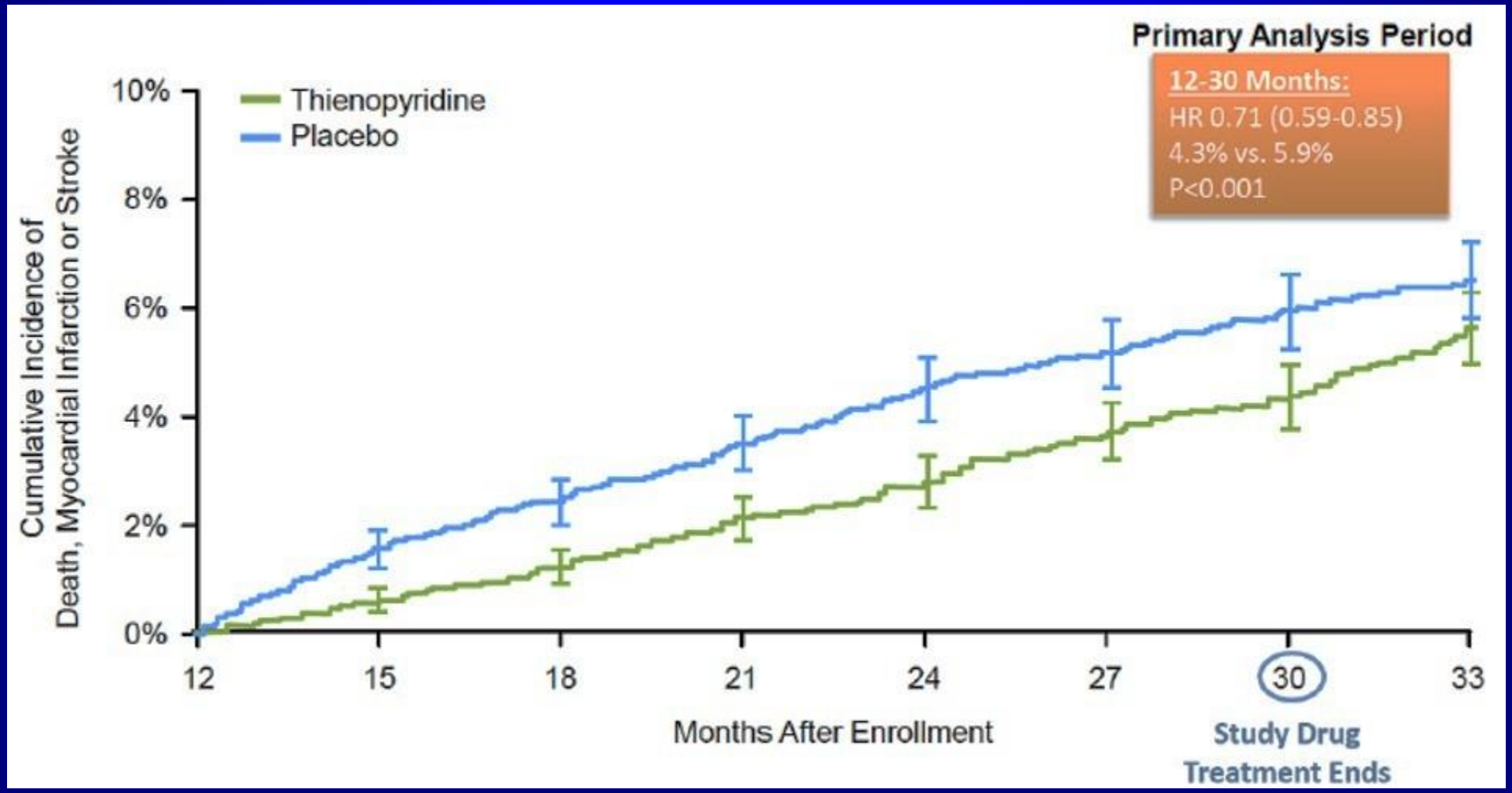
Desfecho Eficacia – Trombosis Definitiva/Probable e MACCE

Desfecho de Seguridad – Sangrado Moderado/Severo (GUSTO)

Mauri L. N Engl J Med 2014;371:2155-2166

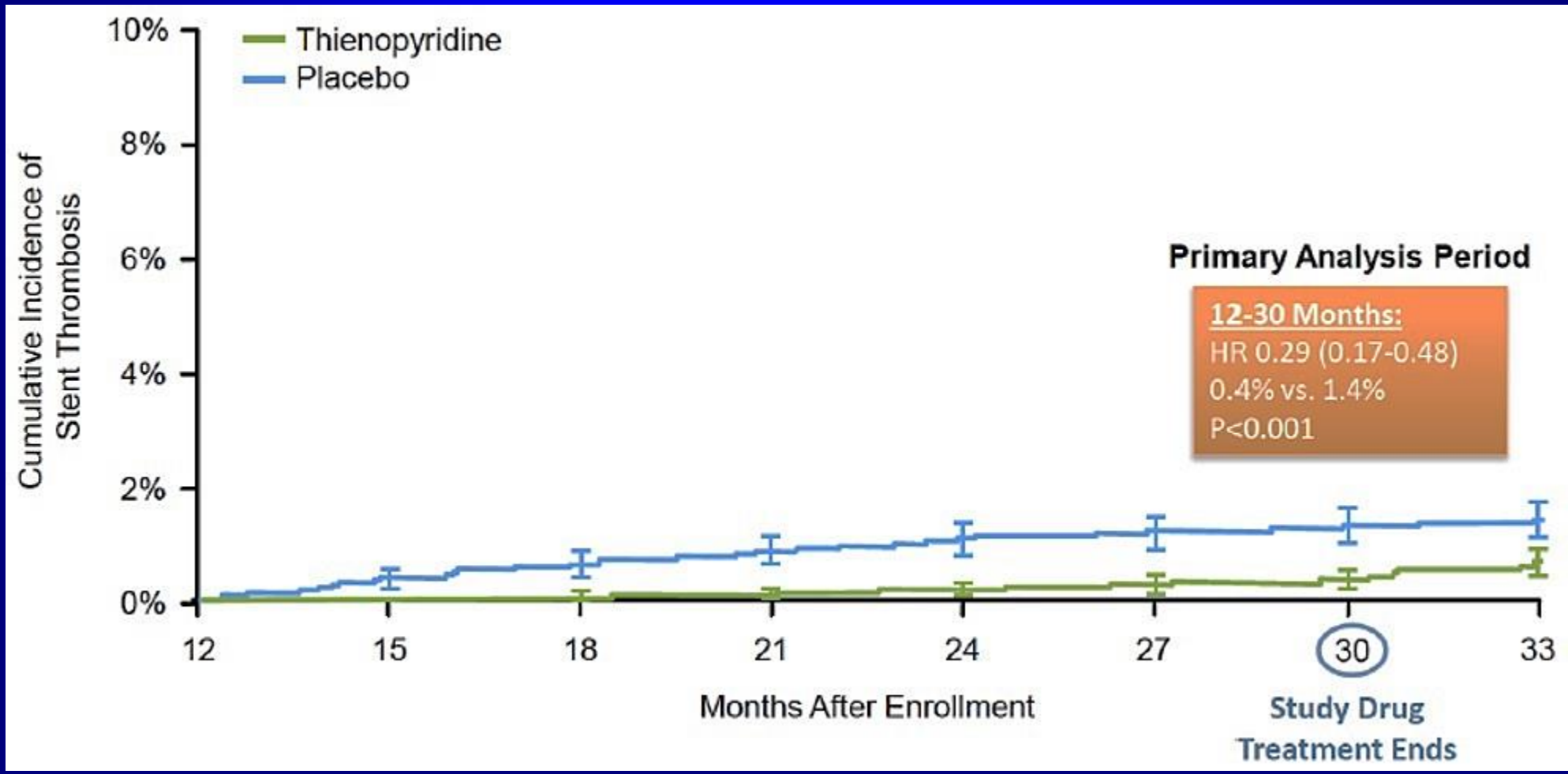
DAPT STUDY

Co-Primary Endpoint - MACCE



Mauri L. N Engl J Med 2014;371:2155-2166

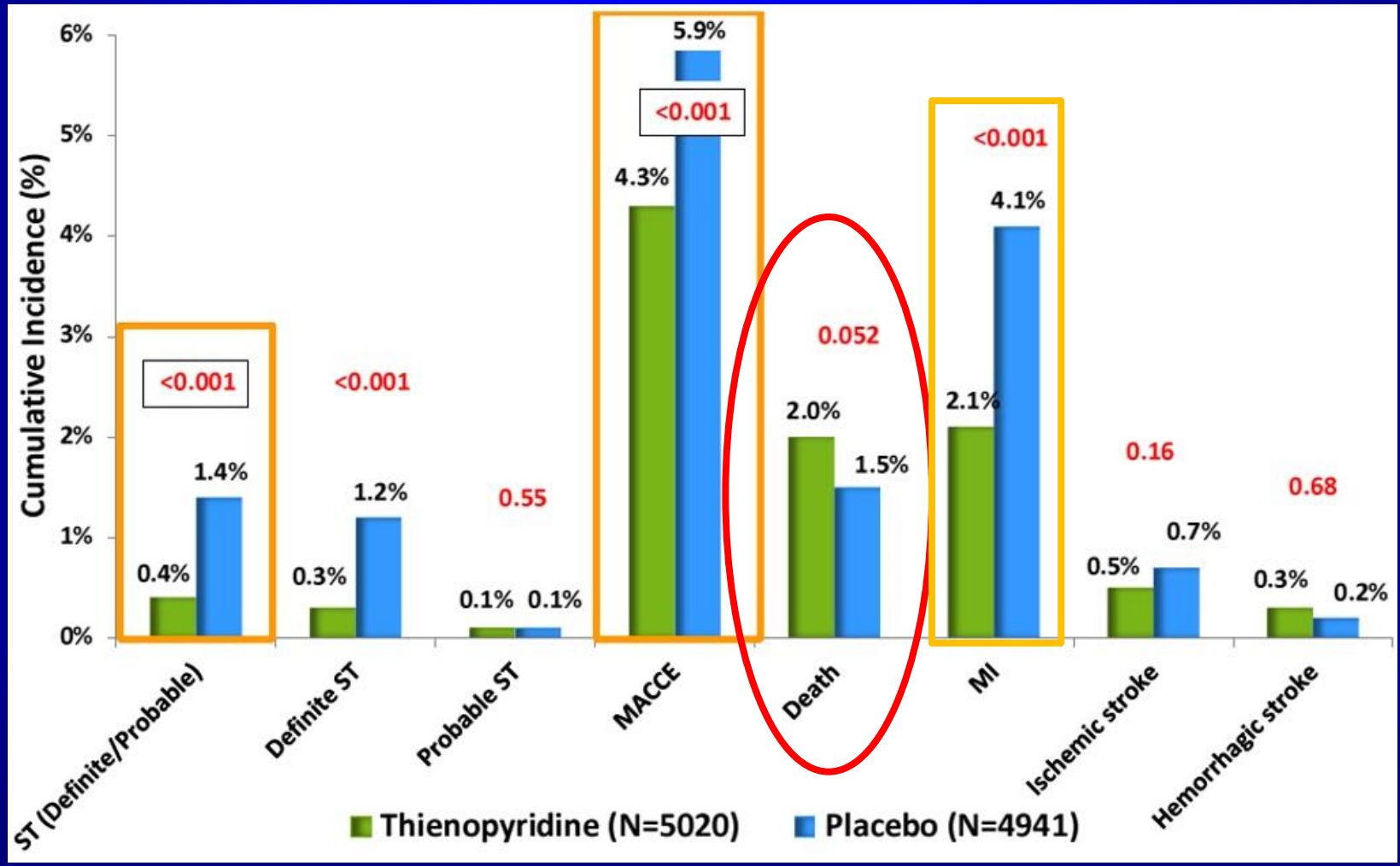
DAPT STUDY
Co-Primary Endpoint



Mauri L. N Engl J Med 2014;371:2155-2166

DAPT STUDY

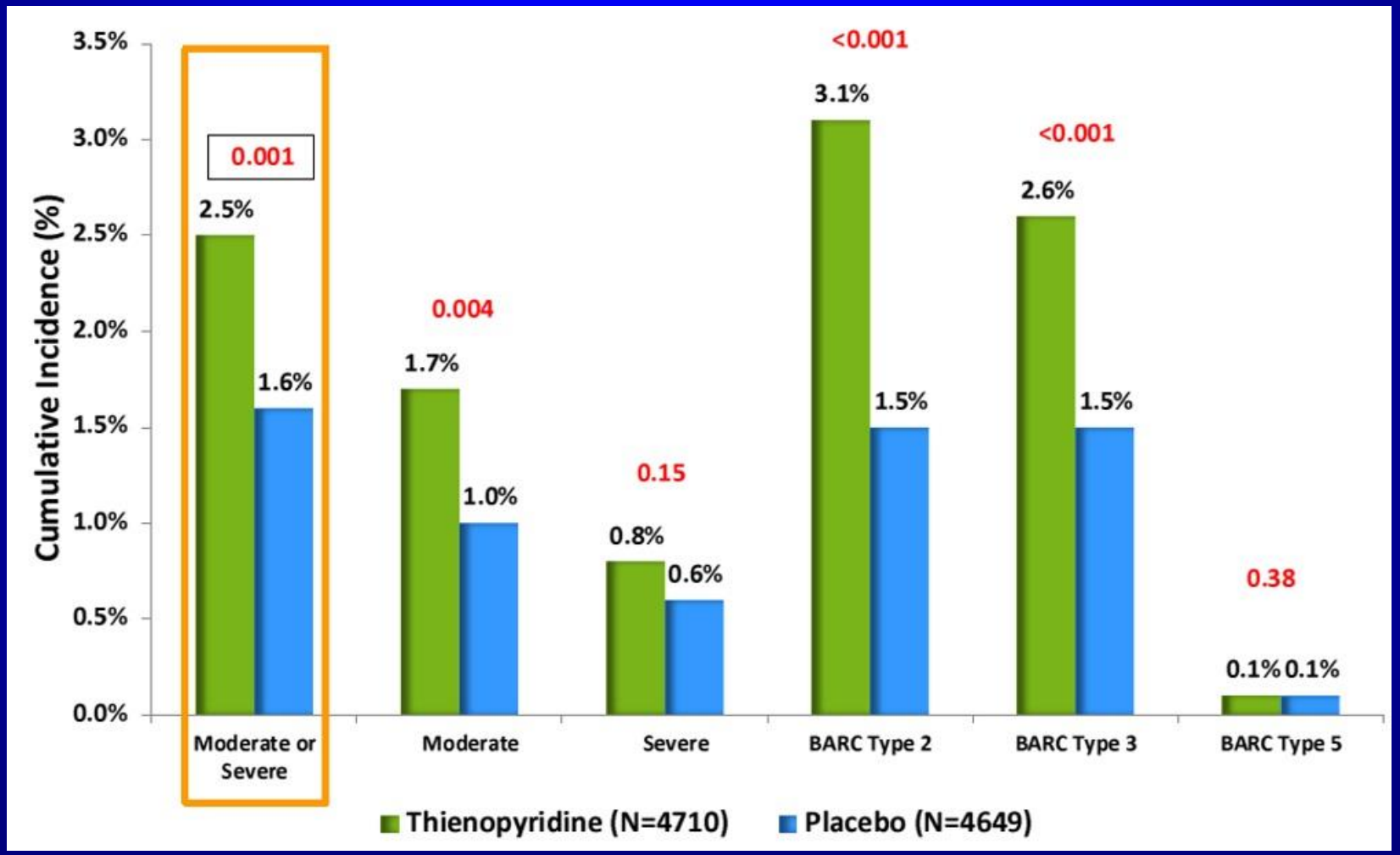
Componentes del Endpoint



Mauri L. N Engl J Med 2014;371:2155-2166

DAPT STUDY

Endpoint de Seguridad



Mauri L. N Engl J Med 2014;371:2155-2166

DAPT STUDY
Endpoint de Seguridad

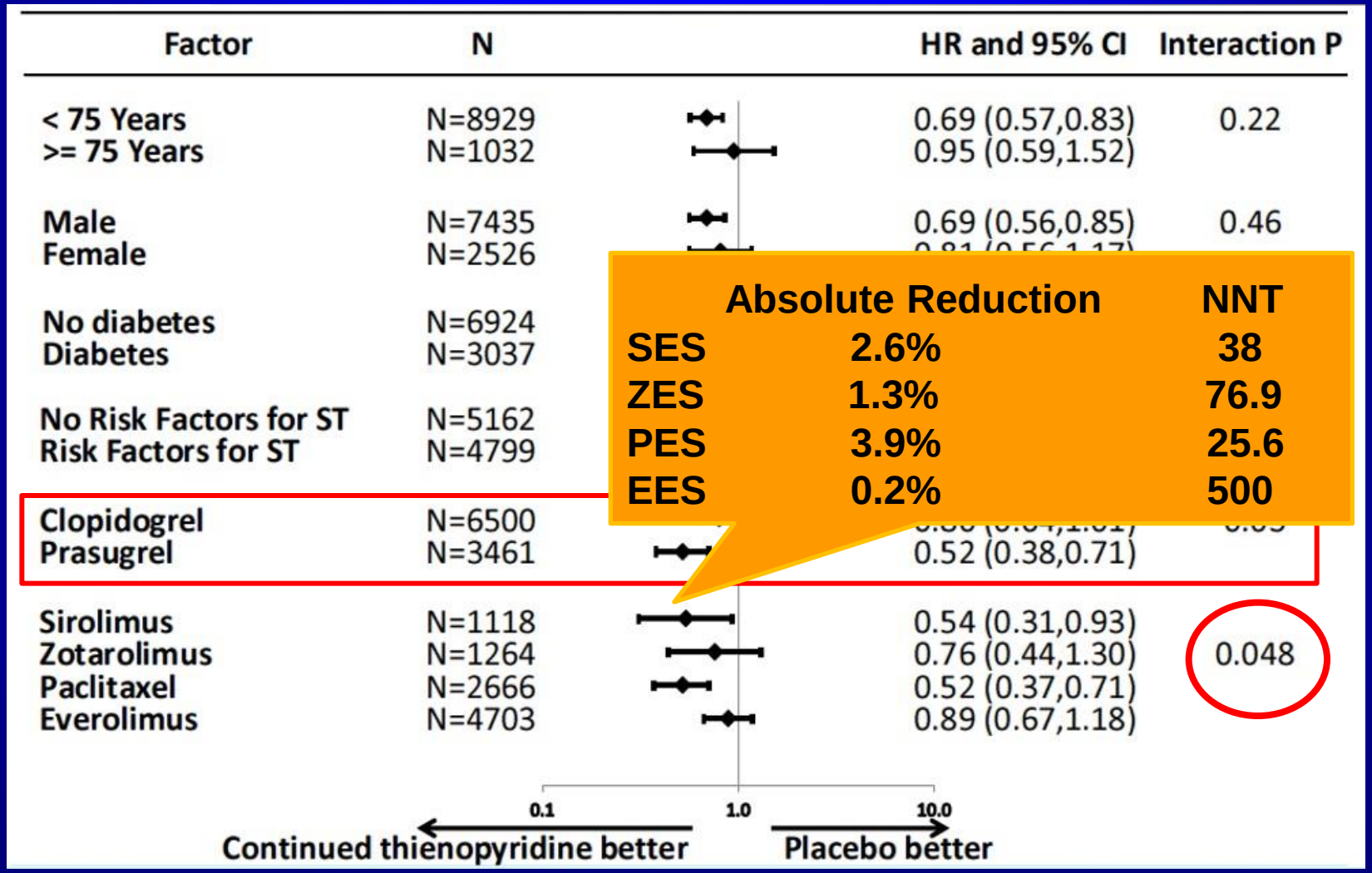
12-30 Months				
	Thienopyridine N=5020	Placebo N=4941	P-Value	Absolute Difference
All-Cause Mortality	**98 (2.0%)**	**74 (1.5%)**	**0.052**	**24 (0.5%)**
Cardiac	45 (0.9%)	47 (1.0%)	0.98	-2 (-0.1%)
Vascular	5 (0.1%)	5 (0.1%)	0.98	0 (-)
Non-Cardiovascular	48 (1.0%)	22 (0.5%)	0.002	26 (0.5%)

Non-Cardiovascular Deaths, 12-33 Months			
Relatedness for Deaths*	Thienopyridine N=5020	Placebo N=4941	P-value
Bleeding-Related Death	11 (0.22%)	3 (0.06%)	0.057
Trauma-Related Death	9 (0.18%)	2 (0.04%)	0.07
Cancer-Related Death	31 (0.62%)	14 (0.28%)	0.02

Mauri L. N Engl J Med 2014;371:2155-2166

DAPT STUDY

MACCE - Subgrupos



Mauri L. N Engl J Med 2014;371:2155-2166

DAPT TRIAL
Conclusiones

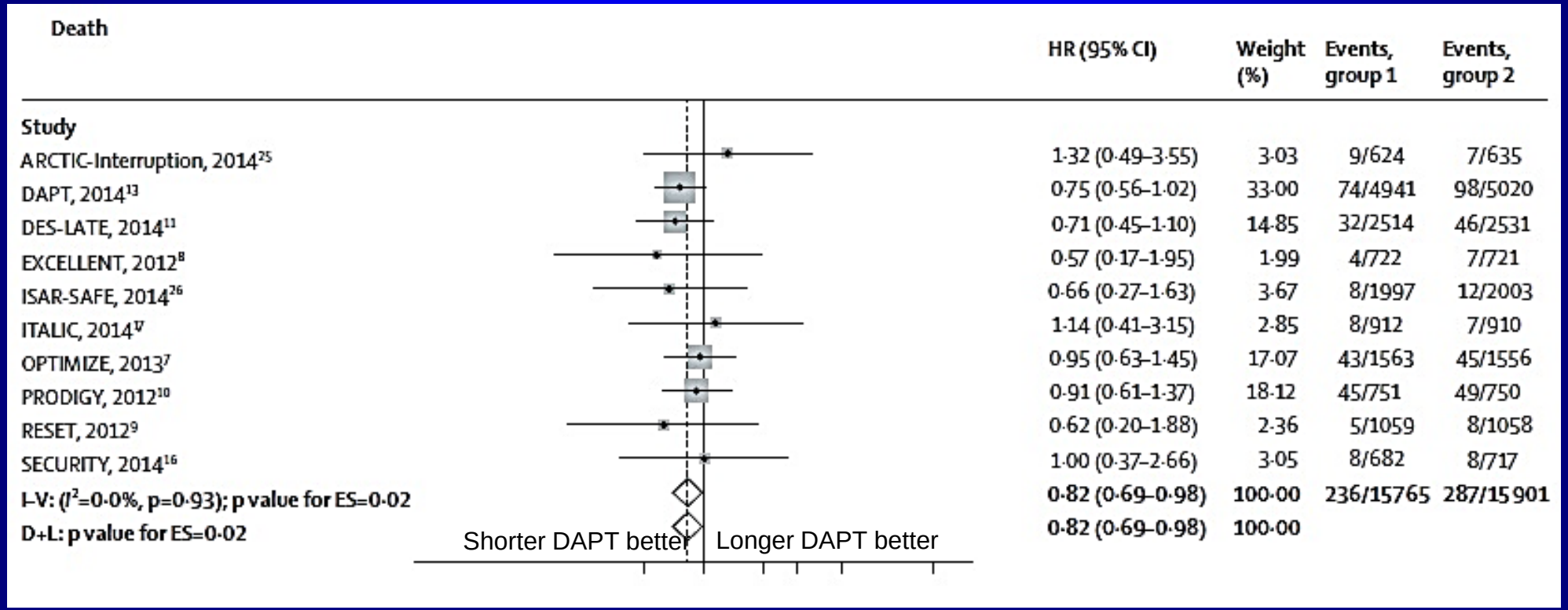
La duración de la DAPT por más de 12 meses proporciono:

- **Una reducción en la taja de MACE y trombosis de los stents as costas de una elevación significativa de 61% en los sangrados moderados/graves.**
- **Ocurrió una fuerte tendencia a una mayor mortalidad (non-cardíaca). Una substancial parte de este aumento debido a los sangrados.**
- **Una significativa interacción entre los tipos de stents y la taja de MACCE sugiere que estas observaciones pueden non ser validas para los stents de segunda generación.**

Estudios DAPT

Meta-análisis - Mortalidad

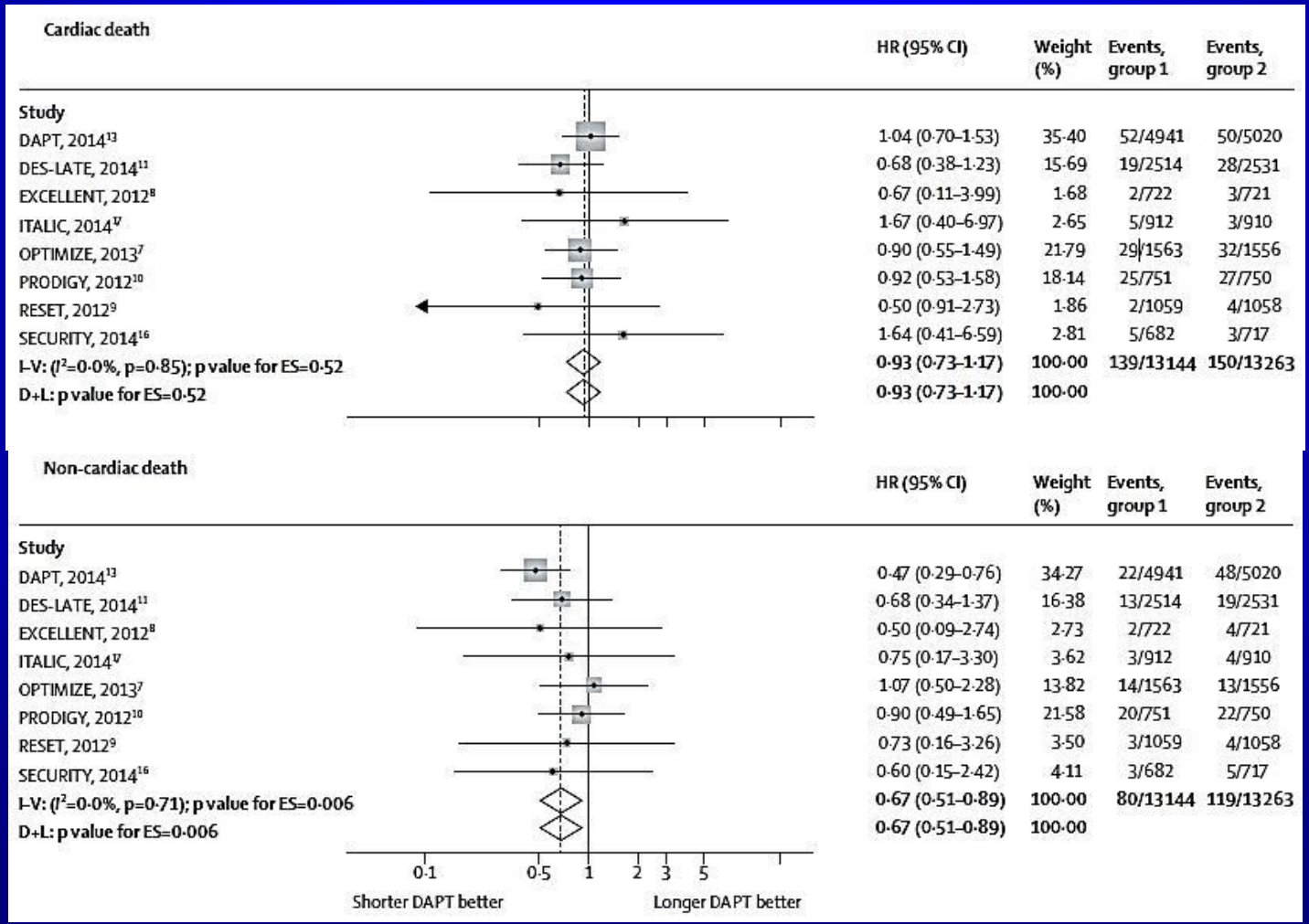
10 Estudios ICP con SF n = 31.666



Palmerini T. Lancet 2015;385:2371-82

Estudios DAPT

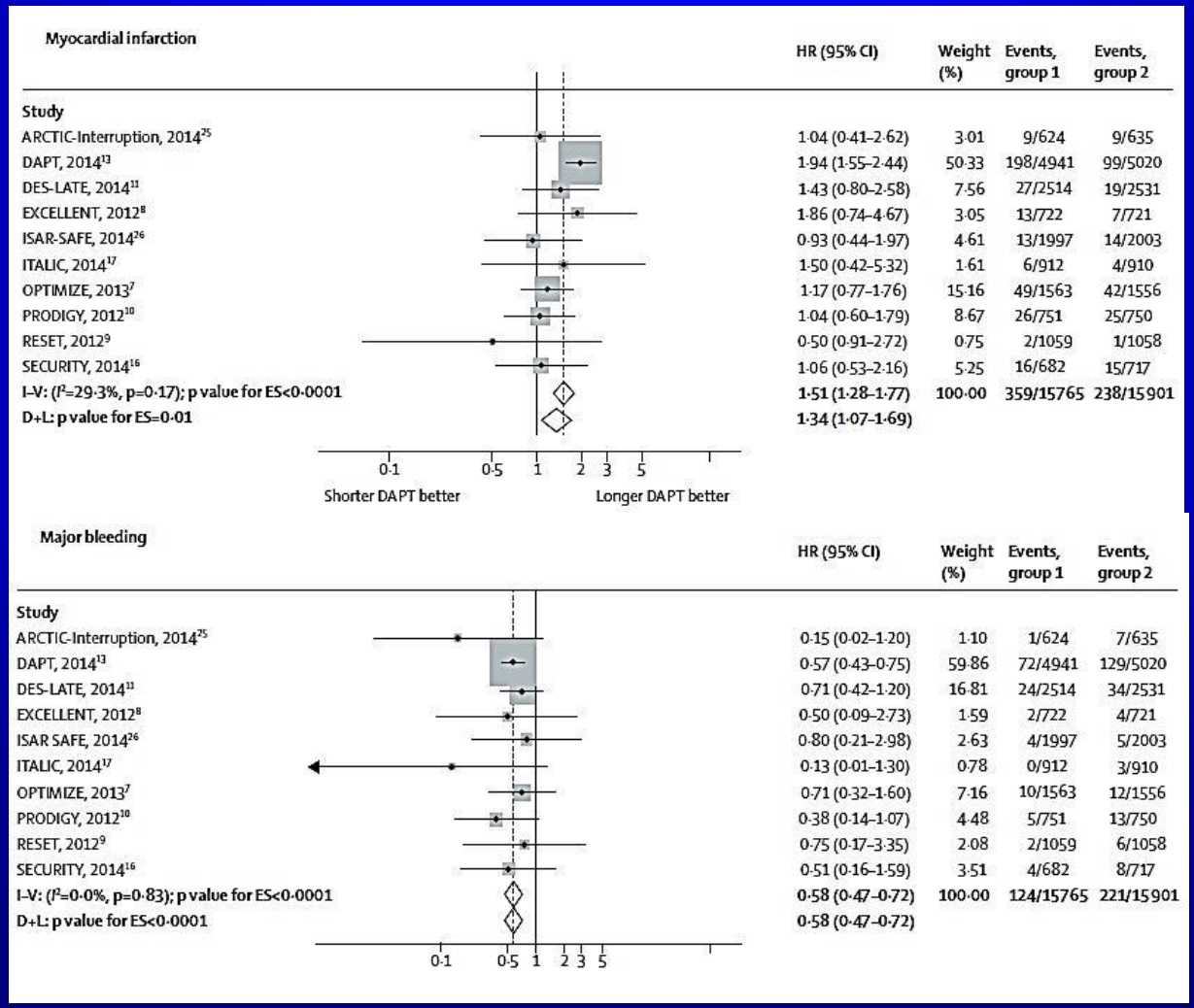
Meta-análisis - Mortalidad



Palmerini T. Lancet 2015;385:2371-82

Estudios DAPT

Meta-análisis – IAM Y Sangrado



Palmerini T. Lancet 2015;385:2371-82

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PMCID: PMC4410620

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Optimal duration of dual antiplatelet therapy after percutaneous coronary intervention with drug eluting stents: meta-analysis of randomised controlled trials

Eliano Pio Navarese, associate professor of medicine and interventional cardiologist,[✉1,2] Felicita Andreotti, associate professor of medicine and cardiologist,[2,3] Volker Schulze, interventional cardiologist,[1,2] Michalina Kołodziejczak, research fellow,[1,2,4] Antonino Buffon, associate professor of medicine and interventional cardiologist ,[3,2] Marc Brouwer, director of research and cardiologist,[5,2] Francesco Costa, research fellow,[6] Mariusz Kowalewski, research fellow,[2,7] Gianfranco Parati, professor of medicine and cardiologist,[8] Gregory Y H Lip, professor of medicine and cardiologist ,[9,2] Malte Kelm, professor of medicine and director of department,[1,2] and Marco Valgimigli, associate professor of medicine and interventional cardiologist[6]

10 Estudios Randomizados n = 32.287

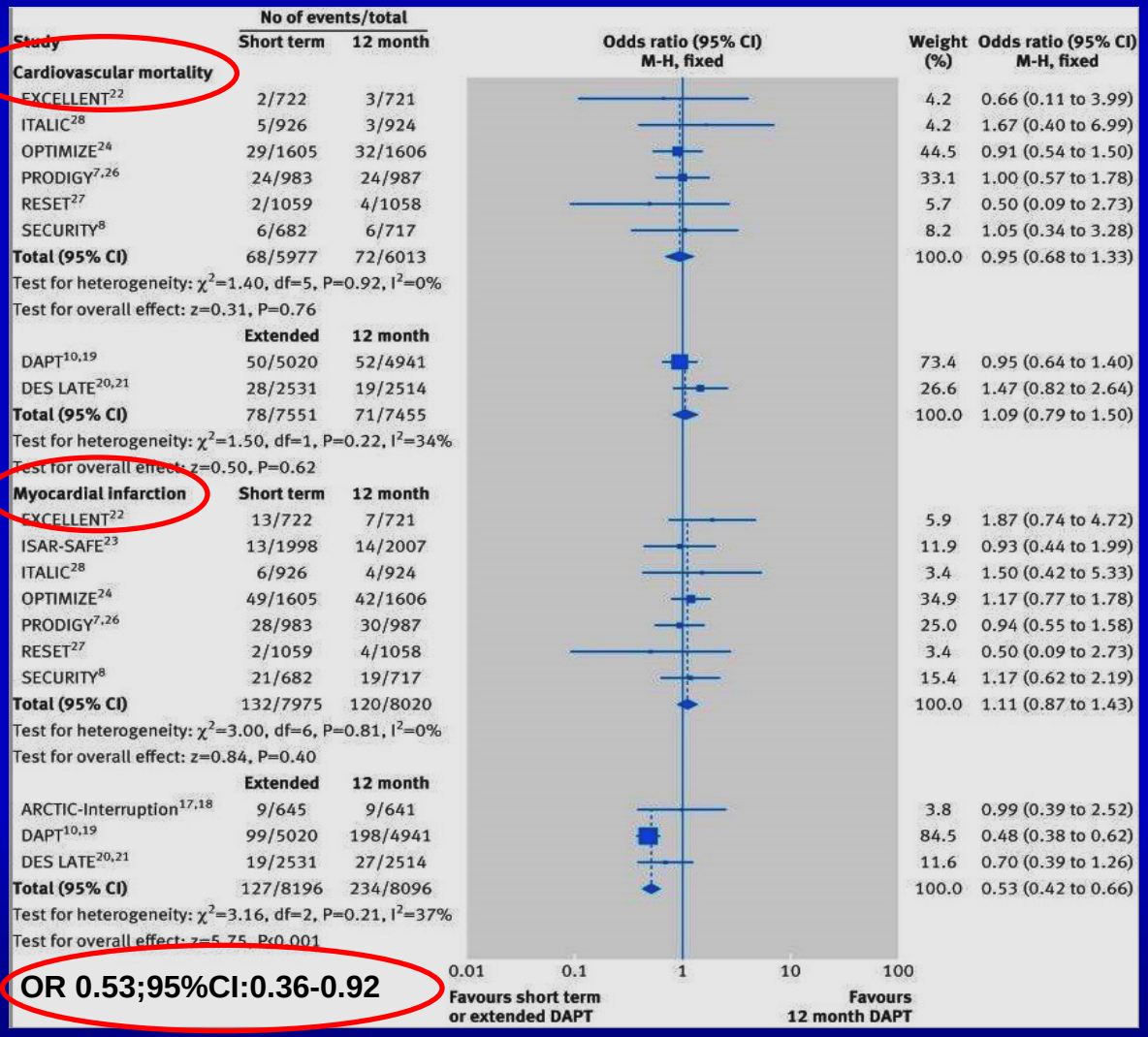
2 Comparaciones

I – Short Term < 12m vs 12 m

II – Extend > 12 m vs 12 m

Comparación Short o Extend vs 12 m

Mortalidad CV y IM

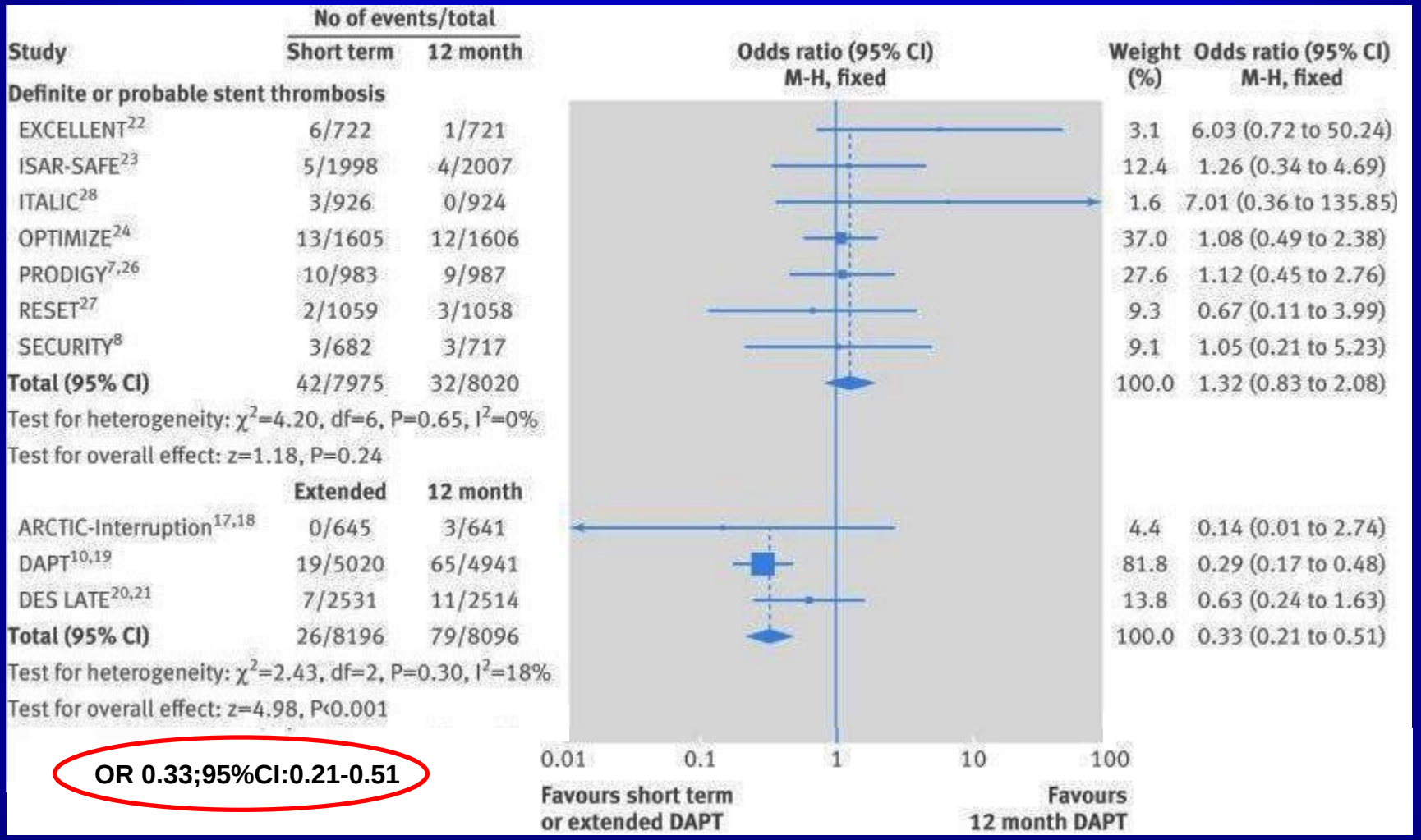


Study	No of events/total: Short term	12 month	Weight (%)	Odds ratio (95% CI) M-H, fixed
Cardiovascular mortality				
EXCELLENT[22]	2/722	3/721	4.2	0.66 (0.11 to 3.99)
ITALIC[28]	5/926	3/924	4.2	1.67 (0.40 to 6.99)
OPTIMIZE[24]	29/1605	32/1606	44.5	0.91 (0.54 to 1.50)
PRODIGY[7,26]	24/983	24/987	33.1	1.00 (0.57 to 1.78)
RESET[27]	2/1059	4/1058	5.7	0.50 (0.09 to 2.73)
SECURITY[8]	6/682	6/717	8.2	1.05 (0.34 to 3.28)
Total (95% CI)	68/5977	72/6013	100.0	0.95 (0.68 to 1.33)
Test for heterogeneity: χ^2=1.40, df=5, P=0.92, I^2=0%				
Test for overall effect: z=0.31, P=0.76				
	Extended	**12 month**		
DAPT[10,19]	50/5020	52/4941	73.4	0.95 (0.64 to 1.40)
DES LATE[20,21]	28/2531	19/2514	26.6	1.47 (0.82 to 2.64)
Total (95% CI)	78/7551	71/7455	100.0	1.09 (0.79 to 1.50)
Test for heterogeneity: χ^2=1.50, df=1, P=0.22, I^2=34%				
Test for overall effect: z=0.50, P=0.62				
Myocardial infarction	**Short term**	**12 month**		
EXCELLENT[22]	13/722	7/721	5.9	1.87 (0.74 to 4.72)
ISAR-SAFE[23]	13/1998	14/2007	11.9	0.93 (0.44 to 1.99)
ITALIC[28]	6/926	4/924	3.4	1.50 (0.42 to 5.33)
OPTIMIZE[24]	49/1605	42/1606	34.9	1.17 (0.77 to 1.78)
PRODIGY[7,26]	28/983	30/987	25.0	0.94 (0.55 to 1.58)
RESET[27]	2/1059	4/1058	3.4	0.50 (0.09 to 2.73)
SECURITY[8]	21/682	19/717	15.4	1.17 (0.62 to 2.19)
Total (95% CI)	132/7975	120/8020	100.0	1.11 (0.87 to 1.43)
Test for heterogeneity: χ^2=3.00, df=6, P=0.81, I^2=0%				
Test for overall effect: z=0.84, P=0.40				
	Extended	**12 month**		
ARCTIC-Interruption[17,18]	9/645	9/641	3.8	0.99 (0.39 to 2.52)
DAPT[10,19]	99/5020	198/4941	84.5	0.48 (0.38 to 0.62)
DES LATE[20,21]	19/2531	27/2514	11.6	0.70 (0.39 to 1.26)
Total (95% CI)	127/8196	234/8096	100.0	0.53 (0.42 to 0.66)
Test for heterogeneity: χ^2=3.16, df=2, P=0.21, I^2=37%				
Test for overall effect: z=5.75, P<0.001				

OR 0.53;95%CI:0.36-0.92

Navarese E. BMJ 2015;Apr 16. Ahead of Print

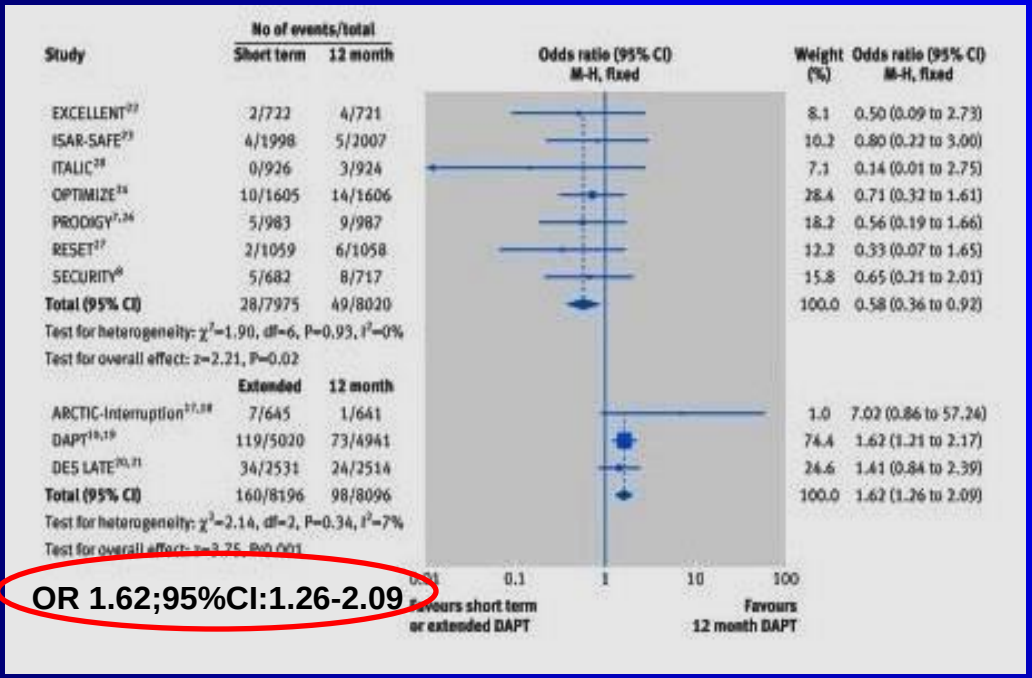
Comparación Short o Extend vs 12 m
Stents Trombosis



OR 0.33;95%CI:0.21-0.51

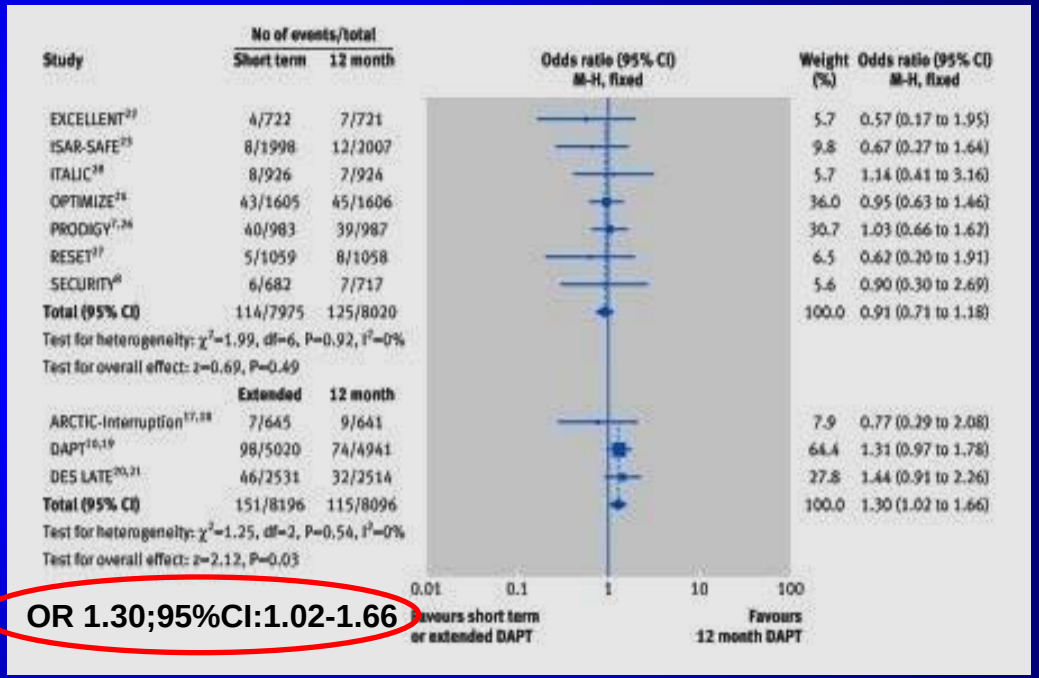
Navarese E. BMJ 2015;Apr 16. Ahead of Print

Comparación Short o Extend vs 12 m
Sangrado y Mortalidad Total



OR 1.62;95%CI:1.26-2.09

Sangrado



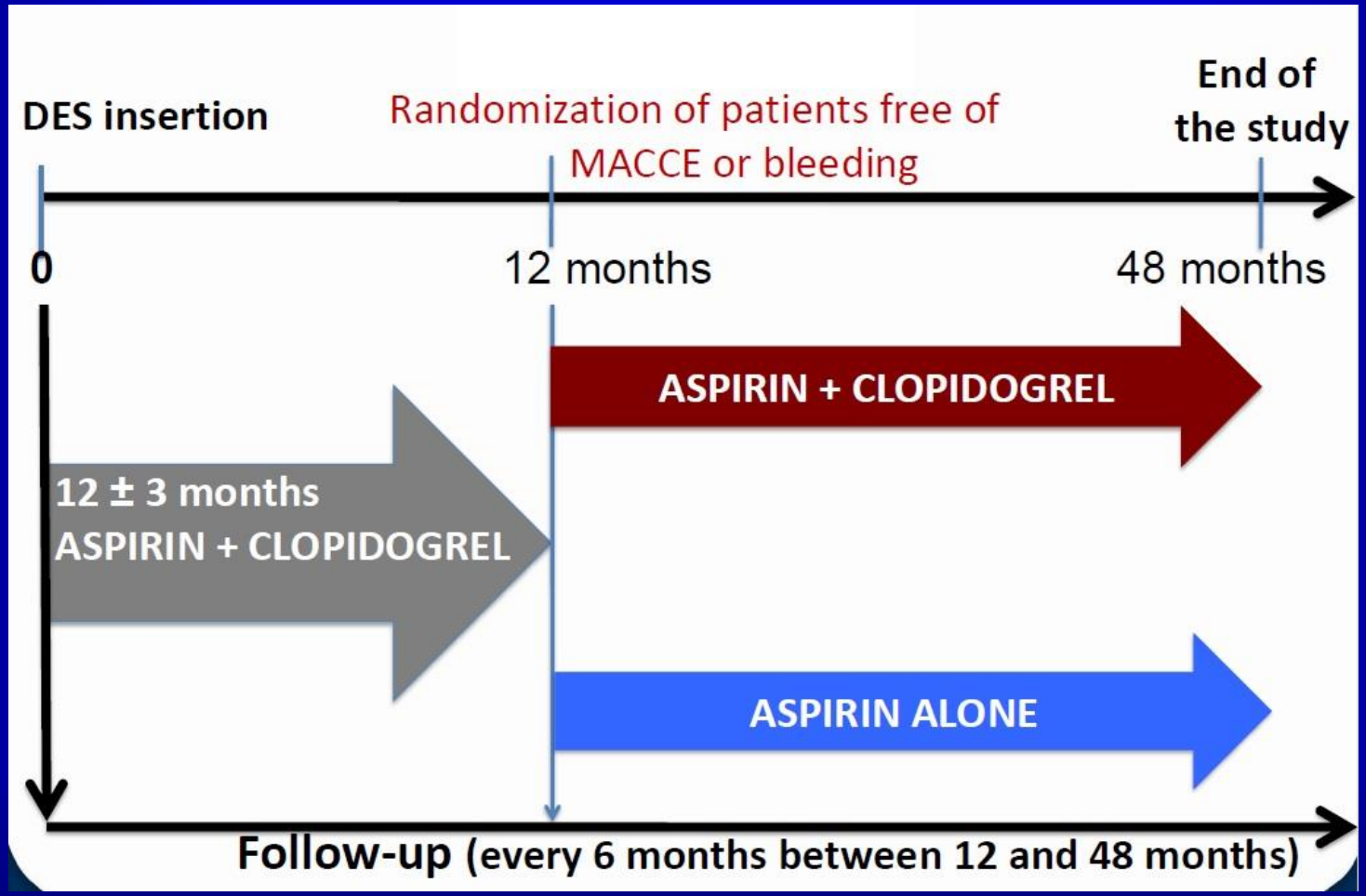
OR 1.30;95%CI:1.02-1.66

Mortalidad

Navarese E. BMJ 2015;Apr 16. Ahead of Print

OPTIDUAL TRIAL
Diseño de lo Estudio

n = 1.398 58 Centros Francia Enero/2009 a Enero/2013



Gérard Helft ESC/2015

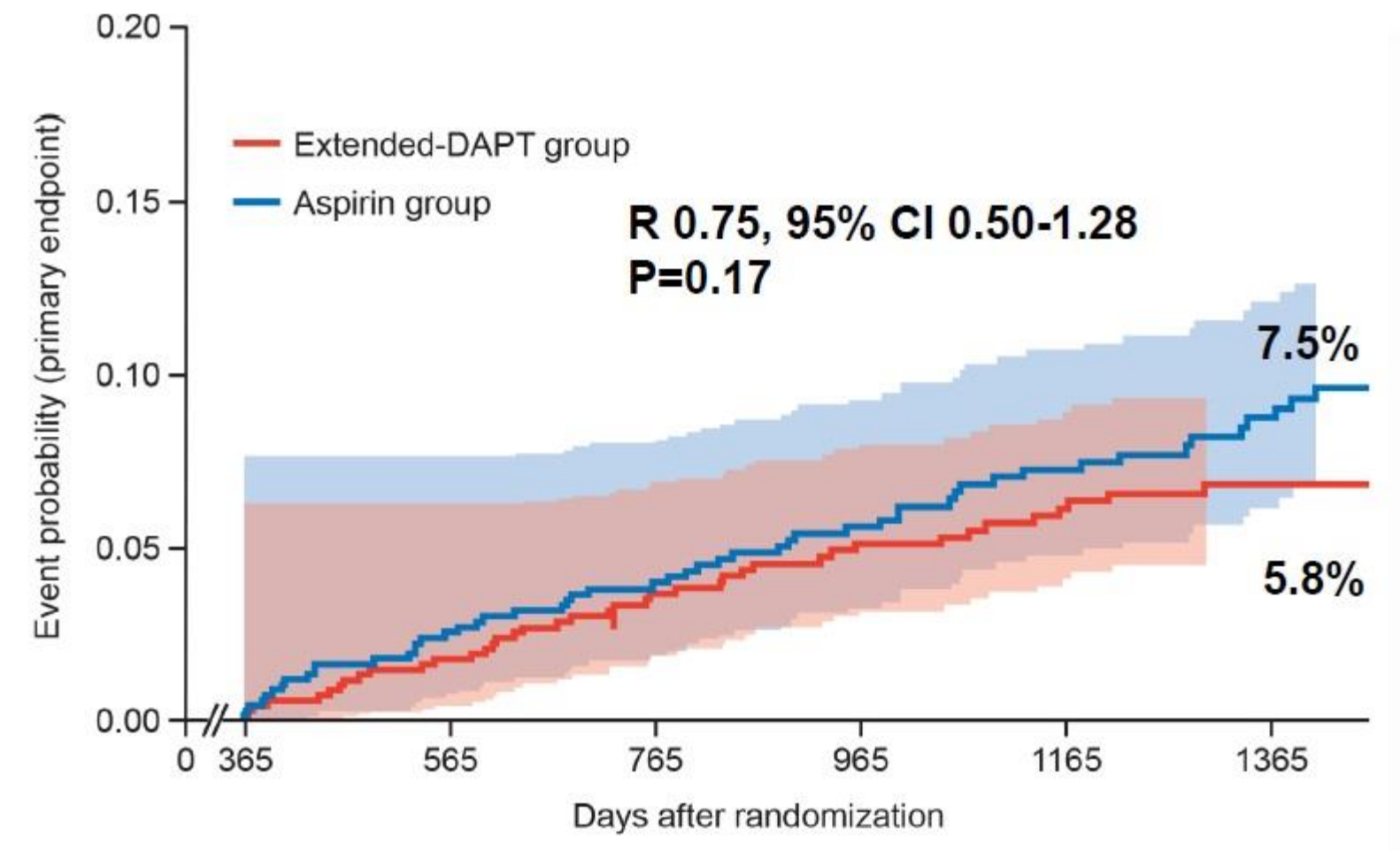
OPTIDUAL TRIAL
Características Básicas

	EXTENDED DAPT GROUP n=695		ASPIRIN GROUP n=690		P value
Indication for PCI					
STEMI	10.7%		11.9%		0.47
Non-STEMI	14.2%	34.4%	17.0%	38.0%	0.39
Unstable angina	9.5%		9.1%		0.81
Stable angina	34.5%		30.0%		0.07
Silent ischaemia	19.9%	65.6%	21.9%	62.0%	0.35
Other	11.2%		10.1%		0.63
Type of DES					
Sirolimus	19.9%	35.1%	17.5%	33.5%	0.17
Paclitaxel	15.2%		16.0%		0.65
Zotarolimus	8.3%		10.8%		0.05
Everolimus	50.2%		49.2%		0.66
Other	6.4%		6. 5%		0.93
Target vessel					
Left main	<1%		>1%		0.69
LAD	58%		64%		0.007
LCX	33%		31%		0.59
RCA	41%		39%		0.58

Gérard Helft ESC/2015

OPTIDUAL TRIAL
Endpoint Primario

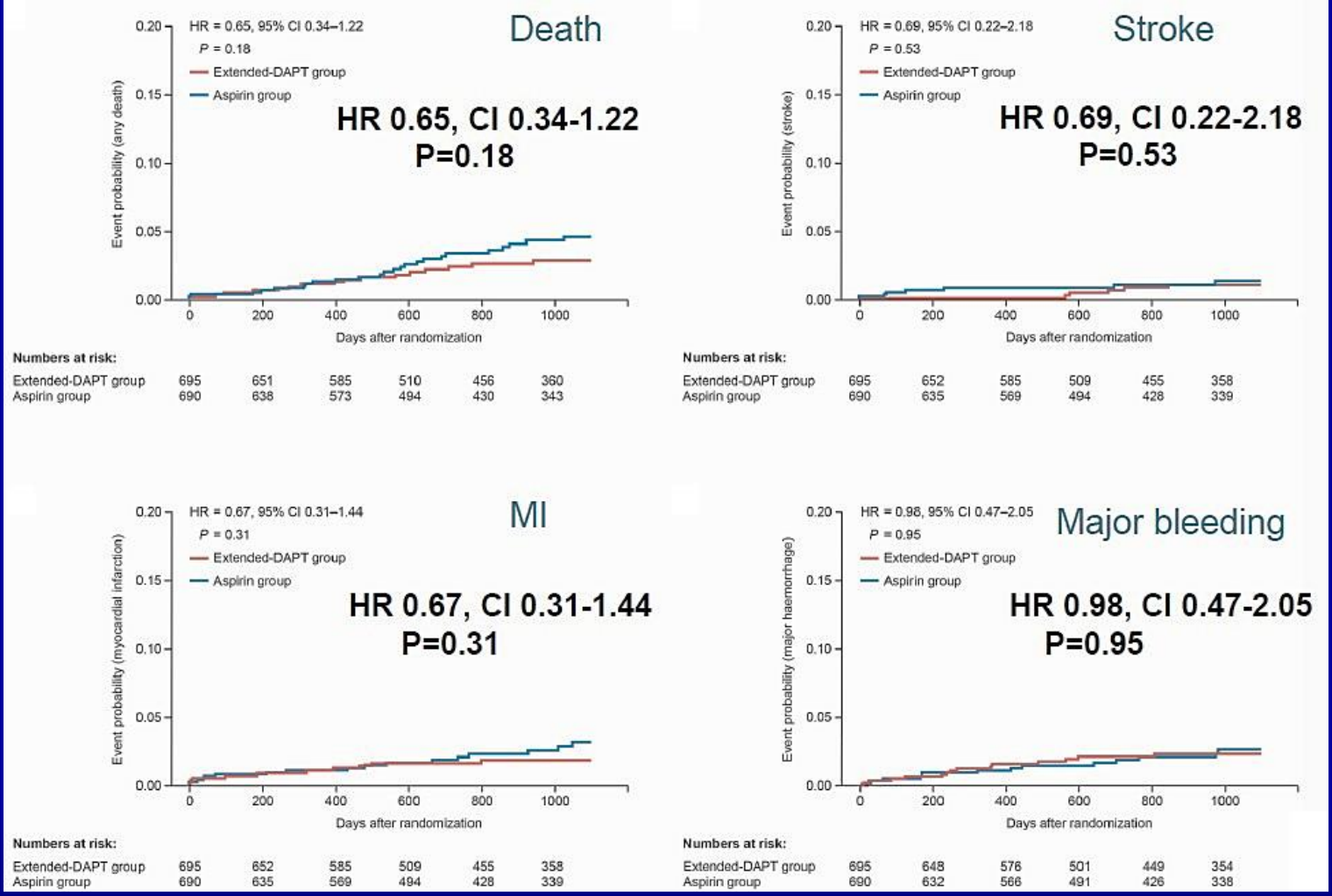
Muerte, IAM, ACV y Sangrado >



Gérard Helft ESC/2015

OPTIDUAL TRIAL

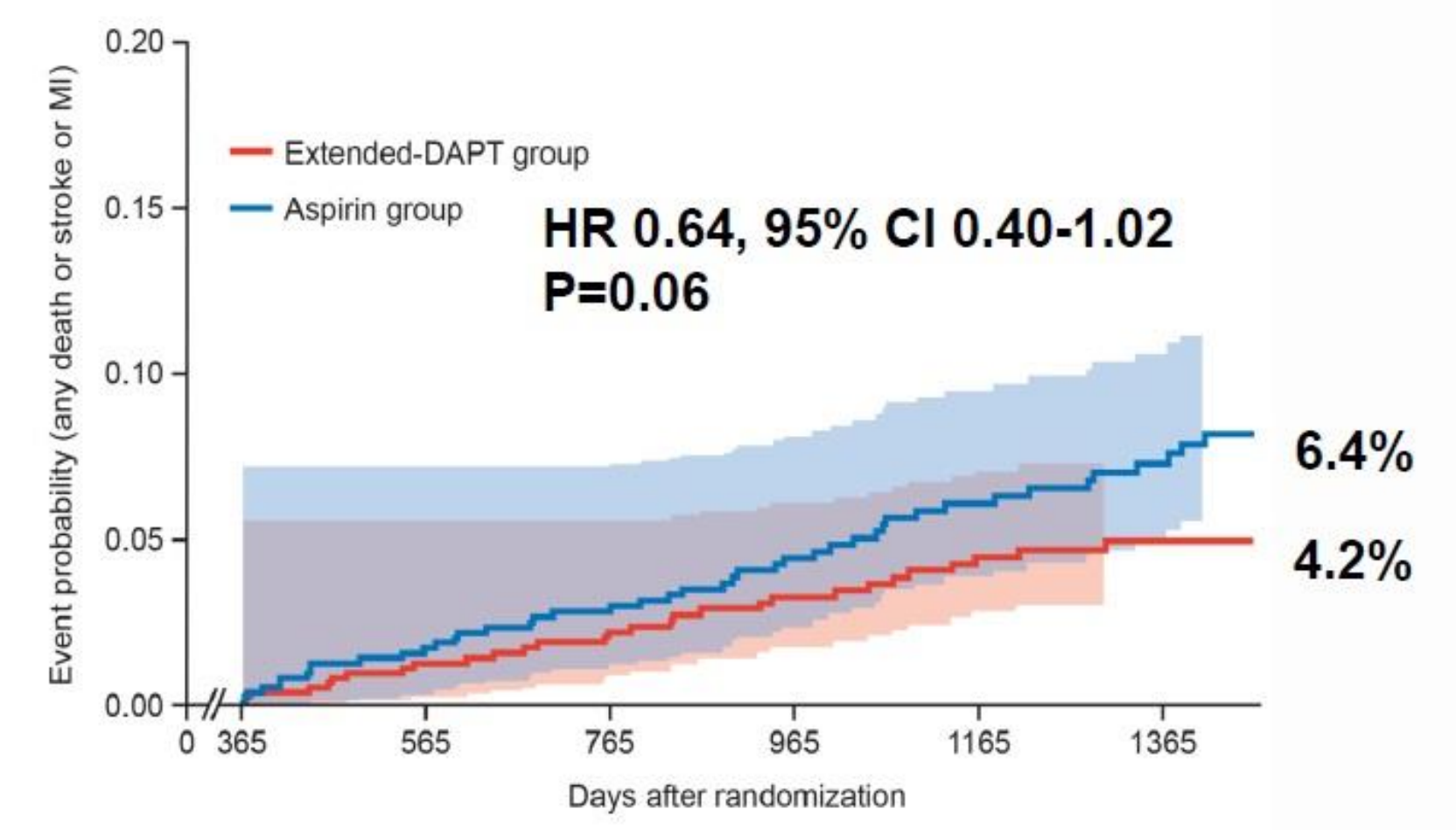
Componentes del Endpoint



Gérard Helft ESC/2015

OPTIDUAL TRIAL

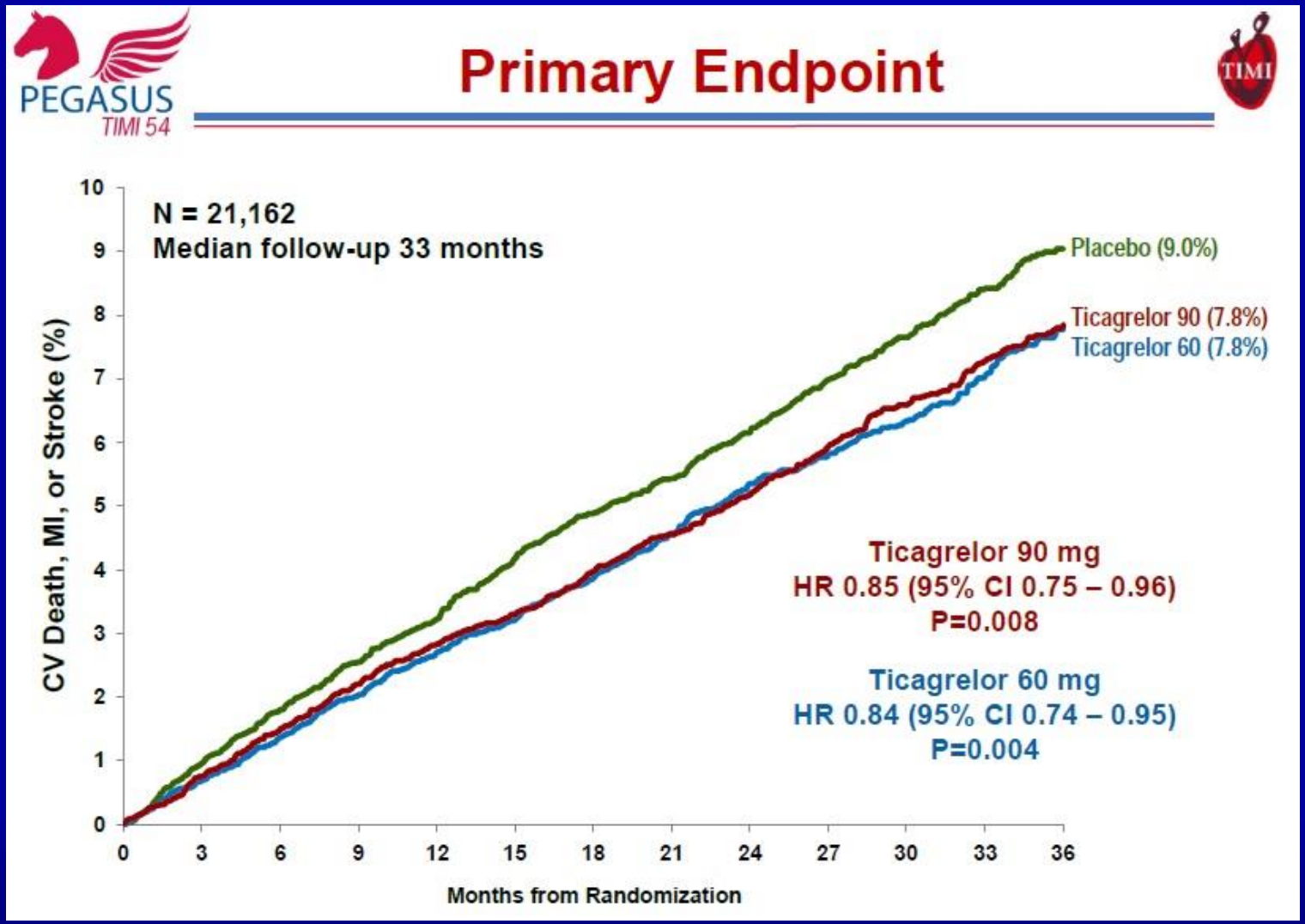
Eventos Isquémicos: Muerte, ACV o IAM



Gérard Helft ESC/2015

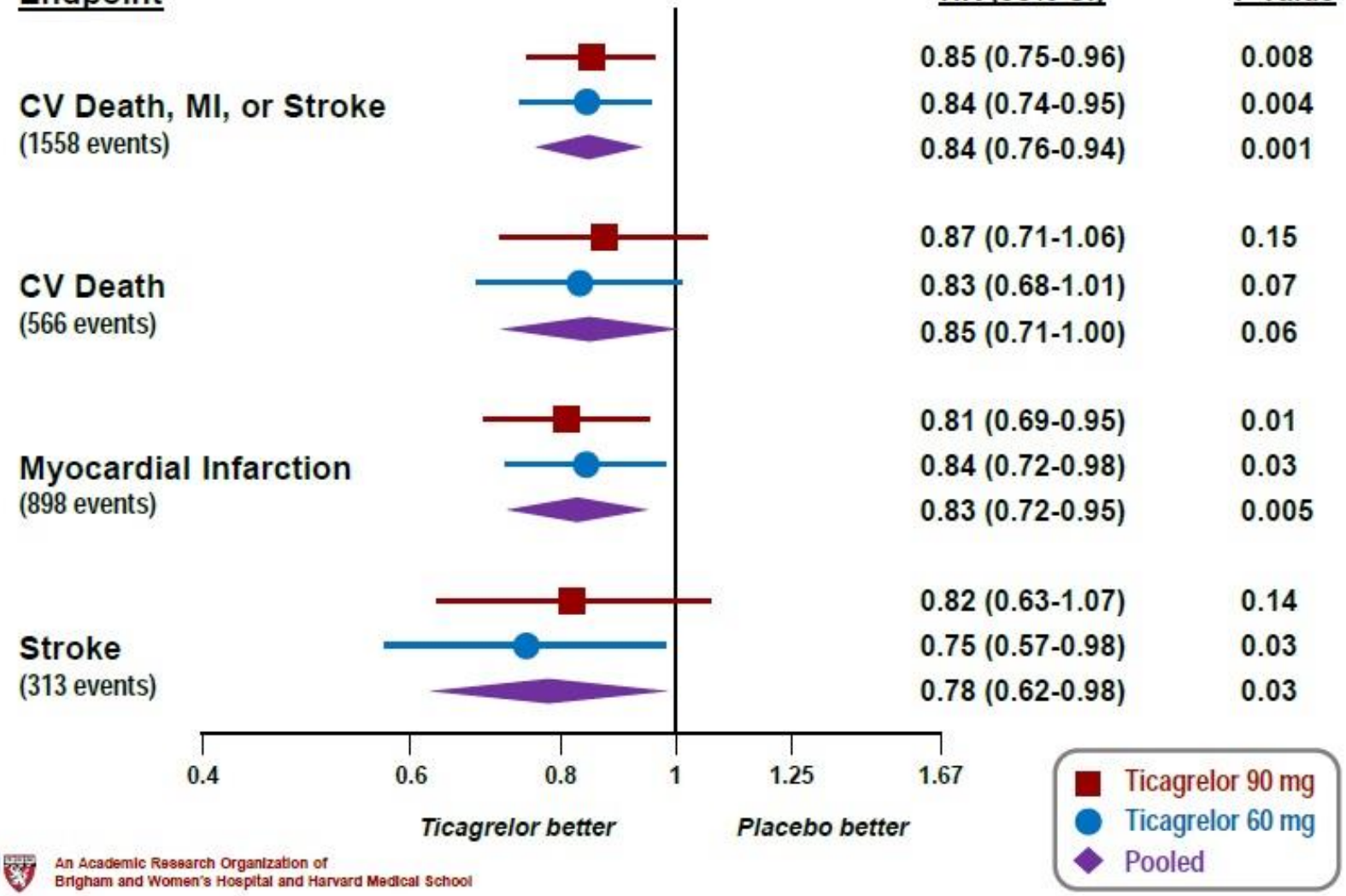
PEGASUS TRIAL – TIMI 54

Eventos Isquémicos: Muerte, IAM o ACV



Bonacca M.P. N Engl J Med 2015;372:1791-1800

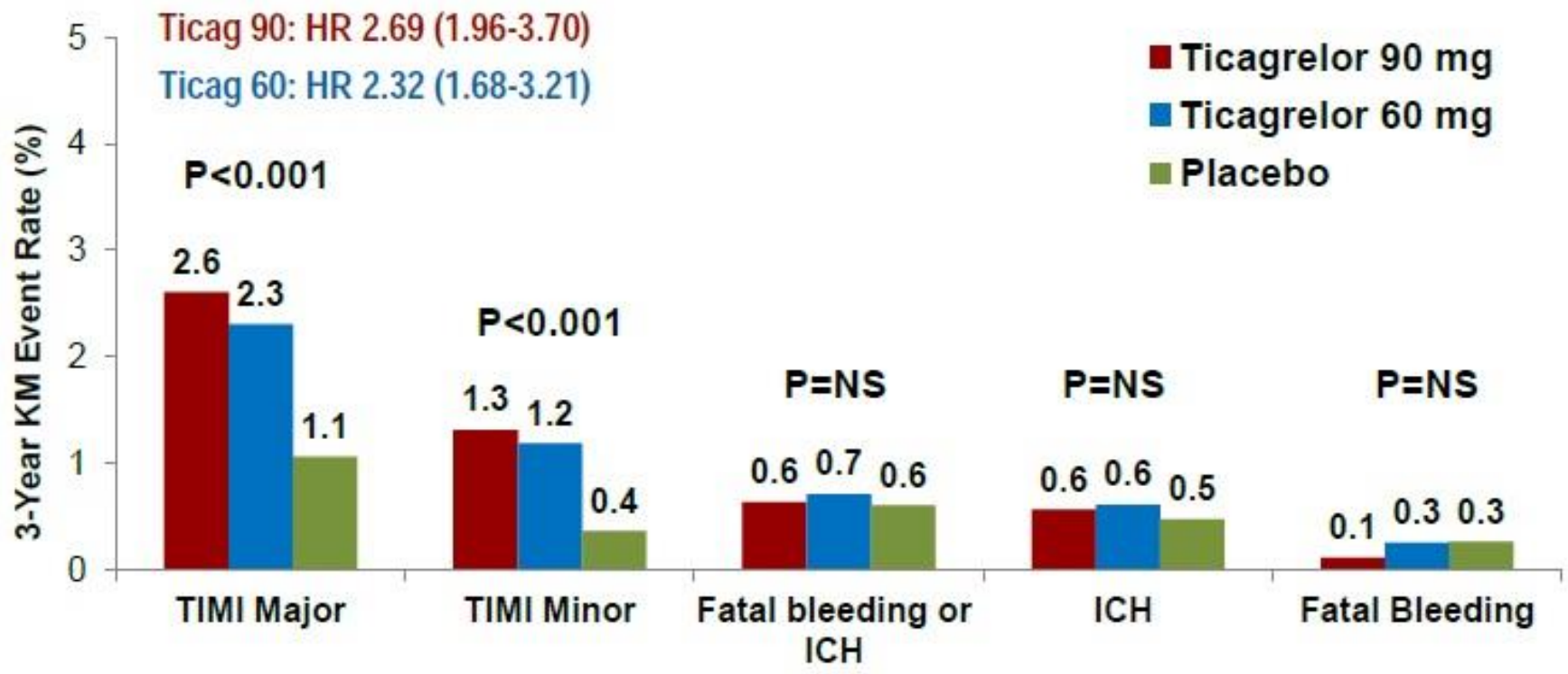
Components of Primary Endpoint



An Academic Research Organization of
Brigham and Women's Hospital and Harvard Medical School

Bonacca M.P. N Engl J Med 2015;372:1791-1800

Bleeding



Bonacca M.P. N Engl J Med 2015;372:1791-1800

Other Efficacy Outcomes

Outcome	Ticagrelor 90 mg bid (N=7050)	Ticagrelor 60 mg bid (N=7045)	Placebo (N=7067)	Ticagrelor 90 vs Placebo p-value	Ticagrelor 60 vs Placebo p-value
	3-yr KM rate (%)				
Coronary Death, MI, or Stroke	7.0	7.1	8.3	HR 0.82 P=0.002	HR 0.83 P=0.003
Coronary Death or MI	5.6	5.8	6.7	HR 0.81 P=0.004	HR 0.84 P=0.01
Coronary Death	1.5	1.7	2.1	HR 0.73 P=0.02	HR 0.80 P=0.09
Death from any cause	5.2	4.7	5.2	HR 1.00 P=0.99	HR 0.89 P=0.14

Bonacca M.P. N Engl J Med 2015;372:1791-1800

Duración da DAPT

Conclusiones

- En general la duración da DAPT después de la ICP con stents farmacológicos debería mantenerse durante 12 m.
- Sin embargo, en pacientes con bajo riesgo isquémico y elevado de sangrado una duración por ≤ 6 m parece apropiada.
- Por otra parte, en pacientes con alto riesgo de trombosis y IAM la duración por > 12 m parece razonable si el riesgo de sangrado es bajo.